

JUN 19 2001

K011187

**Sterling Medivations, Inc.**  
180 Ferndale Road South  
Wayzata, Minnesota 55391  
952-473-7971 (voice)  
952-473-4758 (fax)

**510(k) SUMMARY**

**Date Submitted:** April 17, 2001

**Submitter:** Sterling Medivations, Inc. 180 Ferndale Road South, Wayzata, MN 55391  
Company Phone 952-473-7971, Company Fax 952-473-4758

**Contact:** Joel Douglas, Chief Technology Officer  
Sterling Medivations, Inc.  
Applicant Phone 408-297-9474 ext. 0 voice mail 21 or 650-949-0470  
Applicant Fax 408-297-9473 or 650-949-0342

**Trade Name of Device:** Simplicity™ Soft YP Infusion Set for use with  
the MiniMed Paradigm infusion pumps.  
**Common Name of Device:** Intravascular administration set.  
**Classification Name:** Percutaneous intravascular catheter.

**Predicate Device:** Sterling Medivations Simplicity Soft Y Infusion Set FDA 510(k) K010373 and  
Maersk Medical Paradigm™ Silhouette® Infusion Set, K002138.

**Description of the New Device:** Sterling Medivations Inc.'s ("SMI") Simplicity™ Soft YP Infusion Set is designed to provide a means to infuse or inject medication subcutaneously when attached to the MiniMed Paradigm infusion pump or syringe.

The Simplicity Soft YP Infusion Set is designed for use by people with diabetes to provide a means to infuse or inject medication subcutaneously when attached to the MiniMed Paradigm infusion pump or syringe. It is inserted into the subcutaneous tissue of a patient and the Simplicity P connector is attached to the medication reservoir. This is substantially equivalent to the predicate device and it has the same intended use.

The device consists of four main parts: (1) an infusion catheter made from FEP, (2) an infusion hub that provides the patient the capability of disconnecting the connecting tube from the infusion catheter, (3) a connecting tube and (4) a Simplicity P connector consisting of a needle hub and reusable pump adapter and reservoir connector.

The Simplicity Soft YP Infusion Set is an infusion administration set, connecting to the Paradigm reservoir by means of a Simplicity P connector consisting of a needle hub and reusable pump adapter and reservoir connector and subcutaneously in the patient through an indwelling catheter made of Fluorinated Ethylene Propylene (FEP).. The Sterling Medivations Simplicity Soft YP Infusion Set may be used with any infusion device that delivers continuous or intermittent flow. The connecting tubing is made from a polyethylene tube.

The 25 gauge-indwelling catheter is introduced into the subcutaneous tissue by a removable 27-gauge insertion needle formed from a lumen made of AISI 304 stainless steel. The insertion needle is removed and a connector needle is attached to the hub fixed to the indwelling catheter. This connector needle mates with the indwelling catheter forming a seal that permits the infusion of medication without leakage. The connector needle is made from AISI 304 stainless steel and it is connected to the connecting tubing with a connector housing. The connector tubing proximal end is attached to a Simplicity P connector consisting of a needle hub and reusable pump adapter and reservoir connector for connection to a MiniMed Paradigm pump and reservoir. The connecting tube is solvent bonded to the connector housing and to the needle hub connector.

**Intended Use of the New Device:** The intended use of the Simplicity Soft YP Infusion Set is to provide a means to infuse or inject medication subcutaneously when attached to the MiniMed Paradigm infusion pump or syringe. The Simplicity Soft YP Infusion Set is substantially equivalent to the Sterling Medivations Simplicity Soft Y Infusion Set FDA 510(k) K010373 and Maersk Medical Paradigm™ Silhouette® Infusion Set, K002138.

**Comparison of the Technological Features of the New Device and Predicate Device:**

The Simplicity Soft YP Infusion Set proposed for commercial distribution is similar in all significant respects to the existing Sterling Medivations Simplicity Soft Y Infusion Set FDA 510(k) K010373 and Maersk Medical Paradigm™ Silhouette® Infusion Set, K002138.

The materials and manufacturing processes are substantially equivalent, the labeling is substantially equivalent and it has the same intended use as the Sterling Medivations Simplicity Soft Y Infusion.

The differences that exist between the new and predicate device are as follows:

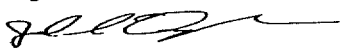
1. The new device proximal end is a Simplicity P connector consisting of needle hub and reusable pump adapter and reservoir connector used to attach to a MiniMed Paradigm infusion pumps and reservoir in place of a Luer fitting.

**Performance Data Supporting Substantial Equivalence:** To prove substantial equivalence both Simplicity Soft YP Infusion Set and Sterling Medivations Simplicity Soft Y Infusion Set FDA 510(k) K010373 meet the catheter requirements of:

- CDRH 21 C.F.R. Section 880.5440 Intravascular administration set
- ISO 10555 Sterile, single use intravascular catheters (Part 1: General Requirements)
- ISO 10555 Sterile, single use intravascular catheters (Part 5: Peripheral Catheters).
- ISO 11135:1994 Medical devices -- Validation and routine control of ethylene oxide sterilization
- ISO 11138-2:1994 Sterilization of health care products -- Biological indicators -- Part 2: Biological indicators for ethylene oxide sterilization.
- ISO 9626: 1991 Stainless Steel needle tubing for the manufacture of medical devices.
- ISO 11607: 1997 Packaging for terminally sterilized medical devices.
- ISO 8535: 1991 Sterile single use syringes, with or without needle, for insulin.
- FDA Guidelines on validation of the Limulus Amebocyte Lysate (LAL) Test as an end product endotoxin test for human and animal parenteral drugs, biological products, and medical devices.
- ODE Blue Book Memorandum #K90-1.
- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing.

And the design process adhered to is the Center for Devices and Radiological Health. DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS. This Guidance relates to FDA 21 CFR 820.30 and Sub-clause 4.4 of ISO 9001. This is substantially equivalent to the predicate device.

Signed,



Joel S. Douglas  
Chief Technology Officer



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 1 9 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Joel Douglas  
Chief Technology Officer  
Sterling Medivations, Incorporated  
180 Ferndale Road South  
Wayzata, Minnesota 55391

Re: K011187  
Trade/Device Name: Simplicity Soft YP Infusion Set  
Regulation Number: 880.5440  
Regulatory Class: II  
Product Code: FPA  
Dated: April 17, 2001  
Received: April 18, 2001

Dear Mr. Douglas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

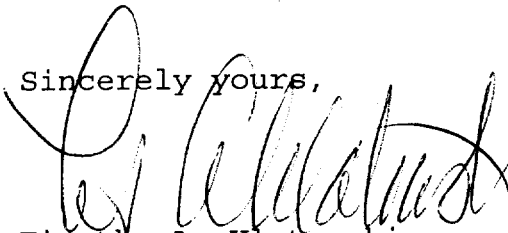
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K011187

510(k) Number (if known): K011187

Device Name: Simplicity Soft YP Infusion Set

Indications For Use:

The intended use of the Simplicity Soft YP Infusion Set is to provide a means to infuse or inject medication or insulin subcutaneously when attached to the MiniMed Paradigm infusion pump or syringe.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

W. Hubbard for Pat Ciccanti

(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K011187